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| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/780,297 | PAPADIMITRIOU, APOLLON | |
| | Examiner | Art Unit | |
| | Chih-Min Kam | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/26/07.
2. ☒ The allowed claim(s) is/are 1,2,4-10,12-16,18,22,29,30 and 40-76.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/853,731.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

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| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
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DETAILED ACTION

Status of the Claims

1. Claims 1-2, 4-10, 12-16, 18, 22, 29-30 and 40-76 are pending.

Applicants' amendments filed December 21, 2006 and January 26, 2007 are acknowledged. Applicants' response has been fully considered. Claims 1, 4, 6, 7, 45, 49 and 73 have been amended, and claims 31 and 39 have been cancelled. Thus, claims 1-2, 4-10, 12-16, 18, 22, 29-30 and 40-76 are examined.

Withdrawn Claim Objections

2. The previous objection to claim 73 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 12 of the amendment filed December 21, 2006.

Withdrawn Claim Rejections-112

3. The previous rejection of claims 1-2, 4-10, 12-16, 18, 22, 29-31, 39-52 and 59-76 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response in the amendments filed December 21, 2006 and January 26, 2007.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

4. The previous rejection of claims 1-2, 4-10, 12-16, 18, 22, 29-31 and 39-76 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 of copending Application No. 09/853,731 based on allowable claims filed June 26, 2006, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response in the amendments filed December 21, 2006 and January 26, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Norman Hanson on February 8, 2007.

Examiner's Amendments to the Claims:

Claims 5 and 44 have been amended as follows:

5. (Currently amended) The composition of claim [[4]] 1 wherein the anion is a sulfate anion.

44. (Currently amended) The composition of claim 43 wherein the antioxidant is methionine which is present in an amount up to 20mM, said composition further comprising having a pH 1-5 % of polyol (w/v).

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention. Bailon *et al.* (U. S. Patent 6,583,272, filed 6/27/2000) teach a conjugate comprising an erythropoietin (EPO) glycoprotein having at least one free amino group and having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells and a poly(ethylene glycol) (peg) group; and a pharmaceutical composition comprising the conjugate, a multiple charged inorganic anion such as sulfate, and a buffer such as phosphate, wherein the EPO glycoprotein can be human EPO having the sequence of SEQ ID NO:1 or 2, or a human EPO sequence modified by addition of 1 to 6 glycosylation sites or a rearrangement of at least one glycosylation site. However, the reference does not teach or suggest the pharmaceutical composition comprising an antioxidant or methionine as an antioxidant. Furthermore, the claimed EPO composition of the instant application containing antioxidant has the priority date of EP 00110355.5, which is 5/15/00, and the claimed EPO composition containing methionine has the priority date of 5/11/2001 (the filing date of parent application 09/853,731), thus the patent by Bailon *et al.* cannot be a prior art reference. Therefore, the claims are allowable over the art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

February 8, 2007